OCT 4 2010

510(K) SUMMARY

Radiancy Ltd.
no!no! Skin™

K102477

7.1.1 Applicant's Name:

Radiancy Ltd.
5 Hanagar Street
Hod Hasharon 45240, Israel
Tel: +972 (9) 775-7500
Fax: +972 (9) 775-7511

7.1.2 Contact Person:

Dr. Rothman Julia
5 Hanagar Street
Hod Hasharon 45240, Israel
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Julia@radiancy.com

7.1.3 Date Prepared: August 18, 2010

7.1.4 Trade Name: no!no! Skin™

7.1.5 Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

7.1.6 Classification: Class II; Product Code GEX;
Regulation No. 878.4810
Panel: General and Plastic Surgery Devices

7.1.7 Predicate Devices: Radiancy Ltd. no!no! Skin™ device cleared under K082423.

7.1.8 Device Description:

The no!no! Skin™ device is an over the counter device employing LHE® (Light & Heat Energy) phototherapy as a part of its fundamental characteristics to treat acne. It is a small, light, hand-held, portable, battery powered devices designed to treat individual acne pimples.

The no!no! Skin™ device consist of an enclosure, a rechargeable battery, an electronic circuit and a low voltage halogen lamp. The treatment tip diameter of 8 mm covers an area of 0.5 cm^2. The energy delivered to the lesion is a combination of focused light emitted from the halogen lamp together and the heat accumulated in the tip placed over the acne lesion.

The user performs the treatment by placing the treatment tip over the lesion and pressing the ON push button to activate one treatment cycle. During the 10 seconds treatment cycle, flashes of light may be seen through the treatment tip. An audio signal indicates the end of the treatment cycle. The device is then removed from the skin, while a green LED flashes for a few seconds, indicating the cool-down period for both the device and the skin. When the flashing stops and a green light appears, the device is ready to deliver another treatment cycle of pulses to the same lesion. The process can then be repeated on another lesion. A second treatment session (consisting of two treatment passes per lesion) may be delivered 6 – 12 hours later.
The user can stop the treatment by pressing the ON button any time during the treatment. Following the conclusion of the treatment session, the device is recharged, using the charger provided with the system. A light indicates that the recharging process is complete, and that the device is 'Ready to Treat'.

7.1.9 Intended Use:

The no!no! Skin™ is intended to provide phototherapeutic light and heat to the body and is generally indicated to treat dermatological conditions. It is specifically indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

7.1.10 Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

7.1.12 Performance Data & Substantial Equivalence

The no!no! Skin™ is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the Radiancy Ltd.'s commercially available no!no! Skin™ device cleared under K082423.

The principle changes between the devices include:

- Annular Cooling Ring (TEC=Thermo electric cooling) –TEC was added around the treatment tip to give a more pleasant sensation during treatment.

no!no! Skin™

- Indication Wording – was edited to better represent LHE technology.
- Battery Change - higher energy type was used to facilitate cooling without increasing the physical dimensions and weight of the device.

A series of safety and performance testing were performed to demonstrate that the modified no!no! Skin™ did not raise any new questions of safety and efficacy. These tests included:

- Electrical Safety testing
- Temperature Evaluation test

Based on the risk analysis performed and these tests results, Radiancy Ltd. believes that the modified no!no! Skin™ device is substantially equivalent to the cleared no!no! Skin™ device and does not raise any new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 4 2010

Radiancy Ltd.
% Dr. Julia Rothman
Clinical Director
5 Hanagar Street
Hod Hasharon 45240, Israel

Re: K102477
Trade/Device Name: No! No! Skin™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OLP
Dated: September 26, 2010
Received: September 29, 2010

Dear Dr. Rothman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K102477

Device Name: no!no! Skin™

Indications for Use:

The no!no! Skin™ is intended to provide phototherapeutic light and heat to the body and is generally indicated to treat dermatological conditions. It is specifically indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___
(Part 21 C.F.R. 801 Subpart D) (Part 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102477